

Translation and Linguistic Validation of the Allergy-CONTROL-Score™ for Use in Japan

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ABSTRACT

Background: Symptom and medication scores are recommended to measure the primary outcome on allergies. The Allergy Control Score was proved to be a valid and reliable instrument to assess allergy severity in clinical trials and may be used in observational studies of respiratory allergic diseases in many countries. We translated the Allergy Control Score and adapted it for use in Japan.

Methods: We translated the original English version into Japanese according to the Mapi approach to linguistic validation: conceptual definition, forward translation by two native Japanese speakers, reconciliation, back-translation by an independent translator, review in consultation with original developer, and pilot testing on 12 patients of an allergy clinic and 3 volunteers with seasonal/non-seasonal allergic rhinitis and/or asthma.

Results: Two of the ten back-translated items needed slight modifications and some words were revised. In the pilot test, the average time required to complete the questionnaire was 55 seconds for the section on symptoms and 25 seconds for the section on medication. All participants were able to self-complete the questionnaire.

Conclusions: By applying the Mapi approach to linguistic validation, we ensured a close match between the Japanese and English versions of the Allergy Control Score. The Allergy Control Score Japanese version is accessible and acceptable to persons with respiratory allergic symptoms in Japan.

KEY WORDS

allergic rhinitis, asthma, Japanese, questionnaire

INTRODUCTION

Symptom and medication scores are recommended to measure the primary outcome of clinical trials on respiratory allergies,¹ and their use is proposed by international regulatory agencies, such as the European Medicines Agency (EMA).² However, validated symptom and medication scores assessing respiratory allergy symptom are currently not available in Japan. The Allergy Control Score (ACS) was developed and has been used successfully in multiple clinical trials in Europe³⁻⁵; it was validated by assessing reproducibility, discrimination capacity, and feasibility

in healthy controls and patients with respiratory allergies.⁶ Convergent reliability analysis indicated a highly significant correlation between ACS and global allergy severity ($P < 0.0001$), quality of life ($P < 0.0001$), and allergy-related medical consultations ($P < 0.0001$). Scores were highly related to pollen counts. ACS showed a good retest reliability ($r = 0.81$; $P < 0.0001$) and discriminated well between patients with allergy and healthy controls with a sensitivity of 97% and a specificity of 87%. Study participants evaluated the feasibility as excellent. The ACS was proved to be a valid and reliable instrument to assess allergy severity in clinical trials and observational studies of

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respiratory allergic diseases.

The objective of the present study was to develop a translated Japanese version of the ACS, with subsequent linguistic validation among Japanese persons with respiratory allergies.

METHODS

MAPI STANDARD LINGUISTIC VALIDATION PROCESS

The Mapi approach to cross-cultural adaptation was referenced and used in this study.⁷ The Mapi Research Institute is an international research organization that engages in translating and validating health-related QOL questionnaire for cross-cultural use.⁸ More than 350 instruments into over 110 languages have been translated and validated internationally there.⁸ We followed their 'standard linguistic validation process', which deals with questionnaire developed in English and needed in another language and/or culture. The Mapi Institute itself was not involved in this study.

'The standard linguistic validation process' of the Mapi Research Institute is composed of the following stages:

- Conceptual definition: the developer of the ACS and the researcher managing the linguistic validation process (the consultant) reviewed all items of the questionnaire to clarify the concepts involved;
- Forward translation: the original instrument was translated into Japanese by two translators, a medical professional and a lay person, both native Japanese speakers proficient in English. The consultant re-conciliated the two translations and established a consensus version;
- Backward translation: the consensus version was back-translated into English by an independent translator who was a native speaker of English and had never seen the original version of ACS. The consultant compared the back translation and the original version and examined any discrepancies between them. These were reviewed by the developer of ACS to produce the pilot version;
- Pilot testing: the Mapi approach pilot testing comprises 2 stages that take place in parallel: cognitive debriefing, where the pilot version is tested with a small sample from the target population (5-10 subjects) to assess its relevance, clarity and intelligibility; and a clinician's review, where an expert clinician reviews and offers feedback on the pilot version.
- Proofreading: two rounds of proofreading ensured the instrument was free of typing, spelling and grammatical errors. This was done, as recommended, by the consultant and one translator.

PILOT TESTING PARTICIPANTS AND PROCEDURE

The study protocol was approved by the Kyoto University Ethics Committee Review Board. The subjects gave a written informed consent and patient anonymity were preserved using documents and methods approved by the ethical review committee.

We recruited subjects with seasonal/non-seasonal allergic rhinitis, allergic conjunctivitis, and/or asthma in Kyoto at a clinic and elementary school. Eligibility criteria included a) suffering from seasonal/non-seasonal allergic rhinitis and/or asthma, and b) not being a medical professional. A letter that included information on the project was given to each participant by their physician (at a clinic), or by the investigator (at an elementary school). Once written consent was given, each participant filled out the following:

- Background information: age, sex, and allergic disease history.
- Pilot version of ACS symptom and medication parts. ACS symptom part consisted of 10 items that covered 3 domains: nasal, eyes, and bronchial symptom. Scores range from 0 to 3 : 0 = absent (no sign/symptom evident); 1 = mild (sign/symptom clearly present, but minimal awareness; easily tolerated); 2 = moderate (definite awareness of sign/symptom that is bothersome, but tolerable); 3 = severe (sign/symptom that is hard to tolerate; causes interference with activities of daily living and/or sleeping). ACS medication part consisted of 2 items; brand name of medication, and dosage on the day.
- Eleven questions on accessibility (e.g., 'Did you find any of the items difficult to understand?'), the content validity and the acceptability of the questionnaire (e.g., 'Do you think you would score high on this questionnaire if you have severe allergic symptom?' 'How difficult was it to respond to the questionnaire?' 'Do you have any suggestions on the questionnaire?').

DATA ANALYSIS

Descriptive analyses were used to assess the quality of the translations. Time to complete and the percentage of missing data were calculated to assess how accessible and acceptable the questionnaire was to participants. We also assessed the accessibility/acceptability/validity of the questionnaire using a feasibility questionnaire given to participants post-pilot. Participants' reactions to the ACS questionnaire items were observed to assess whether they misread any of them, asked for clarification, or needed prompting to answer them. The calculation of the J-ACS was done as described in the original publication of the ACS.⁶

RESULTS

CONCEPTUAL DEFINITION

The consultant reviewed all instructions, items and

Table 1 Answers to feasibility questions

Feasibility Questions	<i>n</i>	0	1	2	3
Do you have any items difficult to understand? (0 = no, 1 = yes)	15	15	0	0	0
Do you have any items difficult to answer? (0 = no, 1 = yes)	15	12	3		
Do you think the items are easy to answer overall? (0 = yes, 1 = no)	15	15	0		
How strenuous was it to respond to the questionnaire? (0 = not at all, 4 = very much)	15	13	2	0	0
How unpleasant was it to answer to the questions? (0 = not at all, 4 = very much)	15	15	0	0	0
Do you think you will have higher score at the questionnaire on the day you have severe allergic symptom? (0 = yes, 1 = no)	15	14	1		
I appraised the content of the questionnaire altogether: (0 = very easy, 4 = very difficult)	15	15	0	0	0
How much did you have to think to answer the single questions? (0 = very little, 1 = little, 2 = some, 3 = much)	15	4	10	1	0
How comprehensible is the instruction on filling out questionnaire? (0 = very easy, 4 = very difficult)	15	13	2	0	0
How comprehensible is the instruction on the application of medication? (0 = very easy, 4 = very difficult)	15	9	6	0	0
Do you have any suggestions to the questionnaire? (0 = no, 1 = yes)	15	15	0		

response choices of the ACS with the developer of the instrument to ensure conceptual clarity.

TRANSLATIONS

The original ACS was translated into Japanese by two native Japanese-speakers. The consensus version of these two translations was then back-translated into English. The back-translated version was compared with the original ACS. The items used in the questionnaire were easily translated, and our results were promising: Eight of the 10 back-translated items were identical to the consensus version and another 2 slightly differed ('watering' to 'tears' and 'itching' to 'ticklishness'). Accordingly, in consensus with original developer, we re-transferred the two, which were then back-translated essentially identical to the original version but with slightly different in wording; 'teary eyes' and 'itchiness (feeling itch)'. Six of the 7 direction sentences were essentially identical in meaning but slightly different in wording. One direction sentence was slightly modified, but the difference was due to the back-translator's error.

PILOT TEST

Clinician's Review

The clinician reviewed the translated ACS and confirmed that the translated version of ACS was appropriate for Japanese patients with respiratory allergies. However, the clinician proposed giving more examples in instruction to make the questionnaire more user-friendly. In fact, the pilot testing revealed that the instructions regarding items related to medications were not very easily comprehensible (Table 1). In consensus with the original developer, we added more examples to the instructions (Supplementary Fig. 1).

Cognitive Debriefing

We administered the first version of J-ACS that included translated items with no diary-styled items to 9 subjects. We then administered the second version

of J-ACS that included the diary style to 6 subjects.

Participants' characteristics—Fifteen subjects with seasonal/non-seasonal allergic rhinitis, and/or asthma were recruited from an allergy clinic and from parents at an elementary school in Kyoto. Participants comprised 2 men and 13 women, with an age range of 16-60 years (mean 41 years, median 40 years). All participants had allergic rhinitis, eight (53%) of which were seasonal, three (20%) with allergic conjunctivitis, and two (13%) with asthma. All subjects completed the questionnaire only once, observed by the investigator at the clinic or at the school. The one-day part of the diary-styled questionnaire was completed within 3 minutes (range: 40-123 seconds, mean 80 seconds; 55 seconds for symptom part and 25 seconds for medication part).

Accessibility and acceptability of the ACS—All subjects were able to self-complete the questionnaire. They all found the questionnaire easy to answer overall and all replied that no items were difficult to understand. Two participants commented that the questionnaire was "slightly strenuous" while the other 13 participants chose "not strenuous at all". Three participants chose that they felt one item was difficult to answer; one felt it was slightly difficult in judging if a symptom was tolerable; another pointed out that he could not judge if he should take into account his cold symptom (sneeze). Because the second version of ACS included a field to comment in that allowed the users to describe their irrelevant symptoms (i.e., cold), we believe the second version of the J-ACS resolves all of the above concerns.

In addition to the above, one participant did not remember her medication name used on that day, but commented that she would have noted the medication if she knew that she was going to be asked. Again another participant did not specify her medication but commented that she could fill in the part once she returned home. The problem of forgetting the name of one's medication could be resolved if the participant was made aware of the need to know this

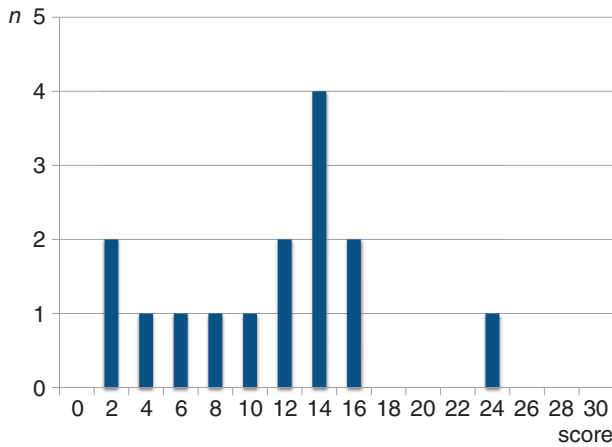


Fig. 1 Distribution of J-ACS scores.

information prior to filling out the questionnaire.

Content validity—No items needed specific clarification. All but one subject commented that it was easy to describe changes in severity of their allergic symptom if the questionnaire once administered daily. One patient with severe seasonal allergic rhinitis commented that she suffered intolerable allergic symptoms daily during the spring, and some of her symptom scores were fixed at 3 during the season, suggesting a ceiling effect. However, once she was explained that ACS uses the total score of all symptoms and medications used on the day, she agreed that her score accurately reflected her symptom severity on the day. Her clinician commented that she suffered from severe seasonal allergic rhinitis, and that her case was an outlier. In fact, the scores of the questionnaire were well distributed across response categories, and this patient had the highest score of all the participants (Fig. 1).

DISCUSSION

This study linguistically validated the Allergy Control Score for use with Japanese people with respiratory allergic symptoms. The Mapi Institute guidelines was referenced and used. Two native Japanese-speakers, a medical professional and a layperson, translated the instrument into Japanese. An independent translator back-translated the consensus version of these two translations into English to check equivalence with the original ACS. We tested the pilot version of the Japanese ACS on 15 subjects with respiratory allergic symptom to evaluate its accessibility, acceptability and content validity. Fifteen subjects recruited to the study, all agreed to take part and all were eligible, making the overall response rate (100%). The accessibility of the J-ACS to subjects with respiratory allergic symptoms is supported by the fact that all respondents were able to complete the questionnaire within 3 minutes. The responses were well distributed across response categories (Fig. 1), suggesting the

questionnaire items would discriminate well between respondents. Although an extremely severe patient pointed out a ceiling effect in the symptom score, she later recognized that her medication score would be added to the total score and that the J-ACS can discriminate everyday changes in symptoms among severe patients. Initial support for content validity for this questionnaire was supported by the fact that no one requested to add information to the questionnaire.

A limitation of this pilot study is its small sample of participants. Although we followed the sample size suggested by the Mapi guidelines ($n = 5-10$), we did not carry out quality controls of data that require large samples sizes, such as estimating Cronbach's alpha. Further validation is needed for use in clinical research aimed to evaluate symptoms of allergic diseases in Japan.

In Japan, nearly 40% of the population is reported to have allergic rhinitis.⁹ Some patients do not regularly consult a physician even though aware of their allergic symptoms. We included such patients in cognitive debriefing, and we did not observe any specific problems in answering the questionnaire. We believe our results can be generalized not only to patients at clinics but also to those with respiratory allergic symptoms who do not regularly consult a physician.

Using the Mapi approach to linguistic validation, this study ensured a close match between the original and Japanese ACS. The Japanese ACS is accessible and acceptable to persons with respiratory allergic symptom in Japan.

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SUPPLEMENTARY MATERIALS

Supplementary Figure 1 is available online.

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